IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

DELINDA KARNES and
RANDY KARNES,

Plaintiffs,

v.

C. R. BARD, INC.,

Defendant.

OPINION AND ORDER

18-cv-931-wmc

Defendant C. R. Bard ("Bard") is the manufacturer of the Align-S Suprapubic Urethral Support System (the "Align-S"). Plaintiffs Delinda Karnes and her husband Randy Karnes brought this lawsuit following Delinda's 2015 surgeries, originally to implant and then to remove the Align-S. Plaintiffs allege products liability, negligence, breach of warranty, fraud, loss of consortium and other claims. Pending before this court is defendant's motion to dismiss under Rule 12(b)(6), arguing that all of plaintiffs' claims are time-barred or, alternatively, that some are deficient. For the reasons set forth below, that motion will be granted in part and denied in part.

FACTS[1]

A. Background

The Karneses reside in Wisconsin. Bard is incorporated in New Jersey, which is also where it has its principal place of business. (Compl. (dkt. #1) ¶¶ 2-3.) Bard develops,

[1] In resolving a motion to dismiss under Rule 12(b)(6), the court takes all of the factual allegations in the complaint as true and draws all inferences in plaintiffs' favor. *Killingsworth v. HSBC Bank Nev.*, 507 F.3d 614, 618 (7th Cir. 2007).

manufactures, produces and sells medical devices, which it promotes and markets "multinational[ly]." (*Id.* ¶ 3.) Bard allegedly controls the "largest share of the hernia mesh market."[2] (*Id.*) Bard designed, manufactured, packaged, labeled, marketed and sold the Align-S that injured Delinda Karnes. (*Id.* ¶¶ 9-11, 22, 24-26, 28-31.)

B. FDA Approval and Warnings about Mesh

The FDA first approved mesh products -- including transvaginal mesh -- to treat stress urinary incontinence ("SUI") in 1996. (*Id.* ¶ 40.) Sometime before 2005, Bard sought and obtained FDA approval to sell the Align-S under 21 U.S.C. § 510(k), because it was "substantially equivalent to a predicate device" marketed before May 29, 1976. (*Id.* ¶¶ 32-37.) However, the FDA issued a "Safety Communication" on July 13, 2011, warning that (1) "serious complications associated with surgical mesh for transvaginal repair of POP [pelvic organ prolapse] are not rare"; (2) "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA"; (3) "literature associate[s] mesh contraction with vaginal shortening, vaginal tightening and vaginal pain"; and (4) "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk." (*Id.* ¶¶ 41-44.)

Contemporaneously with the "Safety Communication," the FDA also issued a white paper, titled *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal*

[2] No definition of that market is alleged, including whether it includes the Align-S.

Placement for Pelvic Organ Prolapse. (*Id.* ¶ 45.) The FDA noted in the white paper that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk," warning that mesh products "are associated with serious adverse events," which were compounded by "performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." (*Id.* ¶¶ 46-47.) As a result, the white paper reiterated that the FDA had "serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse" and advised doctors to "[r]ecognize that in most cases, POP can be treated successfully without mesh." (*Id.* ¶¶ 48-49.)

The complaint goes on to allege that "the FDA assigns a specific 'device problem' code" to "degradation" and "fragmentation." (*Id.* ¶ 54.) More specifically, the FDA allegedly defines: (1) "Material Fragmentation" as an "[i]ssue associated with small pieces of the device breaking off unexpectedly"; and (2) "degradation" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." (*Id.*) According to plaintiffs, "the material from which Defendant's products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the[se] products," which included Delinda Karnes. (*Id.* ¶ 52.)

C. Alleged Defects

Well before Delinda Karnes' surgery in 2015, plaintiffs further allege that Bard "knew or should have known" of the inherent dangers of the Align-S, including those

warned about by the FDA. (*Id.* ¶¶ 38, 50-51.) Likewise, plaintiffs allege that Bard's "products were unreasonably susceptible to shrinkage and contraction," "degradation and fragmentation," and "gradual elongation and deformation when subjected to prolonged tension" inside the body. (*Id.* ¶¶ 54-56.) Despite these risks, plaintiffs allege these products are marketed as being "safe, effective, [and] reliable." (*Id.* ¶¶ 57-59.)

Plaintiffs go on to allege roughly a dozen, specific product defects: (1) "the use of polypropylene and collagen" that causes "adverse reactions and injuries"; (2) the product's design for insertion in a part of the body with high levels of mesh-adhering bacteria; (3) the product's propensity "to contract or shrink inside the body"; (4) the use of arms and anchors "that can injure major nerve routes"; (5) the product's inelasticity that causes pain with normal movement; (6) the likelihood that the product would degrade or fragment once implanted; (7) collagen-producing, hyper-inflammatory responses following implantation; (8) collagen's propensity to disintegrate after implementation; (9) collagen's adverse tissue reactions; (10) "the harshness of cross linked collagen upon the female pelvic tissue, and the hardening of the product in the body"; and (11) a "non-anatomical condition" causing "chronic pain and functional disabilities" following implantation. (*Id.* ¶ 60.)

Finally, plaintiffs also allege that Bard failed to: (1) warn about these and other risks associated with the Align-S; (2) adequately test the effectiveness and safety of the product; (3) adequately train and warn doctors about the product; and (4) design an effective and safe procedure for removal of the mesh. (*Id.* ¶¶ 61-64, 67.)

D. Delinda Karnes' Surgeries

On September 18, 2015, in Eau Claire, Wisconsin, Dr. Michael Hirsh implanted an Align-S in Delinda Karnes to treat pelvic organ prolapse and other symptoms, which the Align-S is designed, marketed and sold to treat. (*Id.* ¶¶ 19, 23.) The Align-S implanted had the following identifying information: Catalog No. BRD200S, Lot No. HUY10031. (*Id.* ¶ 19.) At the time implanted, plaintiffs allege that the Align-S was "in the same or substantially similar condition" as when it left Bard's control. (*Id.* ¶ 68.)

Following implantation, Delinda "experienced significant mental and physical pain, disability, [and] suffering," as well as "permanent injury, and permanent and substantial physical deformity." (*Id.* ¶ 39.) Less than two months after implantation, on November 11, 2015, Delinda had the Align-S removed by Dr. Hirsh. (*Id.* ¶ 20.)

After both implantation and removal of the Align-S, plaintiffs claim economic harm of lost income and medical expenses, as well as Delinda's need for further medical intervention. (*Id.* ¶¶ 39, 77.) In addition to those obvious damages from multiple surgeries and complications, plaintiffs claim that the mesh implant "promote[d] a negative immune response," which inflamed Delinda's pelvic tissue. (*Id.* ¶¶ 52-53.) Plaintiffs further claim to have suffered "impaired physical relations during intimacy, and other damages." (*Id.* ¶ 39.)

OPINION

Defendant seeks dismissal of plaintiffs' claims for failure to state a claim. A motion to dismiss under Rule 12(b)(6) is designed to test the complaint's legal sufficiency. *See* Fed. R. Civ. P. 12(b)(6). Dismissal is warranted only if no recourse could be granted under

any set of facts consistent with the allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 (2007). "To survive a motion to dismiss under Rule 12(b)(6)," a plaintiff must allege sufficient facts to "state a claim for relief that is plausible on its face." *Spierer v. Rossman*, 798 F.3d 502, 510 (7th Cir. 2015) (citing *Twombly*, 550 U.S. at 570).

As this court has emphasized on numerous occasions, the motion to dismiss phase of proceedings "is not an opportunity for the court to find facts or weigh evidence." *My Health, Inc. v. Gen. Elec. Co.*, No. 15-CV-80-JDP, 2015 WL 9474293, at *2 (W.D. Wis. Dec. 28, 2015). The court must "tak[e] all factual allegations as true and draw[] all reasonable inferences in favor of the plaintiffs." *Pugh v. Tribune Co.*, 521 F.3d 686, 692 (7th Cir. 2008). In addition to contending that all of plaintiffs' claims are time-barred, defendant claims the following eight pleading deficiencies: (1) the manufacturing defect claim fails to state a claim under Wisconsin law; (2) the fraudulent concealment claim fails to satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9; (3) the negligent misrepresentation and failure-to-warn claims fail because defendant had no duty to warn under the learned-intermediary doctrine; (4) plaintiffs were not in privity with Bard and did not buy the Align-S directly from it, so their claims for breach of warranties fail to state a claim; (5) plaintiffs' breach of warranty claims are improper because they are asserted with tort claims; (6) plaintiffs cannot establish negligent infliction of emotional distress because there was no physical injury; (7) plaintiffs cannot establish unjust enrichment because they did not provide a direct benefit to Bard; and (8) punitive damages

are not a separate cause of action.[3] After finding that the applicable statute of limitations does not bar suit for the reasons explained below, the court addresses each of these claimed deficiencies below as well.

I. Statute of Limitations

In Wisconsin, the statute of limitations for bodily injury is three years.[4] *See* Wis. Stat. Ann. § 893.54 (1m)(a). Wisconsin follows the "discovery rule" for determining the date on which the cause of action accrued for instances where "negligence and a resulting injury do not occur simultaneously." *S.J.D. v. Mentor Corp.*, 159 Wis.2d 261, 265, 463 N.W.2d 873 (1990) (citing *Hansen v. A.H. Robins Co., Inc.*, 113 Wis.2d 550, 560, 335 N.W.2d 578 (1983)). In such cases, "the statute of limitations begins to run when the potential plaintiff discovers the injury, or in the exercise of due diligence should have discovered the injury." *Id.* at 265-66 (citing *Hansen*, 113 Wis.2d at 560). This means that the cause of action only accrues when the plaintiff "discovers both the nature of his or her injury and its cause," so that "the relationship between the injury and its cause [is] more than a layperson's hunch or belief." *Id.* at 266 (citing *Borello v. U.S. Oil Co.*, 130 Wis.2d 397, 406-07, 412, 388 N.W.2d 140 (1986)). Accordingly, "the relevant inquiry is on the strength *and* the nature of the connection between the defendant's conduct and the injury as reflected in the facts known to the claimant." *Id.* at 267 (emphasis original). More

[3] Since the parties appear to be in agreement that plaintiffs' gross negligence claim should be dismissed (Mot. to Dismiss Br. (dkt. #10) 17-18; Opp'n (dkt. #19) 11), the court will not address it further.

[4] There is a statutory exception to this rule for death or bodily injury resulting from a motor vehicle accident, but that is obviously not applicable here. Wis. Stat. Ann. § 893.54(2m).

specifically, the plaintiff must have an "*objective* basis for determining that the defendant had a role in causing his or her injuries." *Id.* at 269 (emphasis original).

Here, defendant contends plaintiffs "knew or should have known of their injuries allegedly resulting from the implantation of the Align[-S] by no later than November 11, 2015," when it was removed by Dr. Hirsch. (Mot. to Dismiss Br. (dkt. #10) 11.) Indeed, because Delinda opted to have it removed, defendant contends that plaintiffs had reason to determine that the Align-S was "causing Plaintiff's alleged injuries [even] before the November 11, 2015 excision surgery." (Reply (dkt. #22) 6.) Plaintiffs argue the defendant is not far off, taking the position that the statute of limitations began running *on* the date of the removal surgery, so that the last day to timely file suit was November 13, 2018 -- the day plaintiffs filed the complaint -- because November 11, 2018, was a Sunday and November 12, 2018, was a federal holiday. (Opp'n (dkt. #19) 6.)

Accordingly, the question before the court is when plaintiff had an objective basis for determining that Delinda's injury was caused by the Align-S. While plaintiffs' complaint now alleges that the Align-S "caused serious injury and had to be surgically removed," the complaint does not detail when someone in plaintiffs' position would have had an objective basis for determining that defendant's product played a role in causing Delinda's injuries, rather than other complications from the surgery. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, No. 1:17-md-2775, 2018 WL 6067505, at *3 (D. Md. Nov. 19, 2018) (applying in part Wisconsin law) ("Revision surgery, alone, only tells a plaintiff that she is suffering from complications as a result of her implant procedure, but it is silent as to the cause of that complication."); *id.*

at *10 ("[B]ased on the face of the complaint alone, it is not clear what information, if any, the [Wisconsin] plaintiffs received before or after their revision surgeries that might have provided an objective basis for discovering [defendant's] role in causing their injuries"); *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, No. 4:08-MD-2004 (CDL) Case Nos. 4:13-cv-130 (Thielke), 2016 WL 1578755, at *2 (M.D. Ga. Apr. 19, 2016) (granting summary judgment under Wisconsin statute of limitations where plaintiff "had enough information to know of a connection between ObTape and at least some of her injuries" following implant's removal and reduction in symptoms where plaintiff failed to "exercise[] even the slightest diligence . . . by asking her doctors a few questions . . . or by seeking a copy of her medical records," either of which would have revealed the connection).

Accordingly, this is not a case where dismissal on statute of limitations grounds is appropriate at the pleading stage. *See Andonissamy v. Hewlett-Packard Co.*, 547 F.3d 841, 847 (7th Cir. 2008) ("A statute of limitations defense, while not normally part of a motion under Rule 12(b)(6), is appropriate where 'the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense, such as when a complaint plainly reveals that an action is untimely.'" (quoting *United States v. Lewis*, 411 F.3d 838, 842 (7th Cir. 2005)). In particular, there is no indication on this record that plaintiffs had *any* objective reason to suspect defendant's Align-S was a culprit for her post-implantation complications, nor even *after* its removal, though presumably at some point the doctor who removed the mesh determined that the Align-S was a contributory cause of those complications. Accordingly, additional factual development is required to determine

precisely *when* plaintiff had an objective basis for assessing Bard's role in causing her injuries. *Cf. In re Smith & Nephew*, 2018 WL 6067505, at *10 (requiring additional factual inquiry to determine when the cause of action accrued).

II. Pleading Deficiencies

A. Manufacturing Defect

Alternatively, defendant argues that plaintiffs "allege no facts indicating or even suggesting that the Align[-S] deviated in any way from the underlying manufacturing specifications." (Mot. to Dismiss Br. (dkt. #10) 13.) In order to allege a prima facie product defect claim, a plaintiff must only plead five elements:

> (1) that the product was in defective condition when it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause (a substantial factor) of the plaintiff's injuries or damages, (4) that the seller engaged in the business of selling such product . . ., and (5) that the product was one which the seller expected to and did reach the user or consumer without substantial change in the condition it was when he sold it.

Dippel v. Sciano, 37 Wis.2d 443, 460, 155 N.W.2d 55 (1967); Wis. Stat. § 895.047(1). In addition, "[a] product has a *manufacturing* defect when it deviates from the manufacturer's specifications, and that deviation causes it to be unreasonably dangerous." *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 2009 WI 78, 319 Wis.2d 91, 768 N.W.2d 674 (2009) (emphasis added). The additional elements are important because rather than allege a product liability claim generally, plaintiffs broke their claim into separate design and manufacturing defect claims, and defendant effectively concedes that the former is adequately pleaded, while arguing that the latter is not.

In the complaint, plaintiffs identify aspects of the product's "specific nature" and generally allege that the Align-S was "defective" or had "defects," all without identifying any aspect of the product implanted in Delinda that deviated from the intended design. (*See* Compl. (dkt. #1) ¶¶ 58-59, 60-61, 76, 81-82, 93-94, 97-98, 100, 102, 108-09, 111, 113, 116-18, 123-25, 139, 146, 164, 168-69, 184.) In fairness, they include naked assertions that "the product was defectively manufactured," and "Defendant's poor quality control . . . resulted in the non-conformance of the Align-S," but fail to specifically allege *how*. (*Id.* ¶¶ 103, 107.) Tellingly, in their opposition, plaintiffs offer that the Align-S "was defective because it can break apart when implanted in the body" and its "[p]olypropylene is known to be not viable for implantation in the human body." (Opp'n (dkt. #19) 7.) This is not enough to allege a *manufacturing* defect. *Cf.* Wis. Stat. § 895.047(1) ("A product contains a manufacturing defect if the product departs from its intended design.").

As noted above, plaintiffs assert a design defect claim as well, which defendant has not sought to dismiss -- other than on statute of limitations grounds. (*See* Mot. to Dismiss Br. (dkt. #10) 7-8.) "A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1); *see also Godoy*, 2009 WI 78, ¶¶ 28-29 ("[A] determination that a product is *defective* is not identical to a determination that the product was *defectively designed*." (emphasis original)). Accordingly, plaintiffs'

manufacturing defect claim is dismissed without prejudice.[5]

B. Fraudulent Concealment

While Federal Rule of Civil Procedure 8(a) provides the general pleading standard -- "a short and plain statement of the claim" -- fraud must be "state[d] with particularity" under Rule 9(b). Fed. R. Civ. P. 8(a), 9(b). In order to satisfy this heightened pleading standard, a "plaintiff may need to perform pre-complaint investigation to provide 'the who, what, when, where, and how'" underlying the alleged fraud. *Webb v. Frawley*, 906 F.3d 569, 576 (7th Cir. 2018) (quoting *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007)). However, the relevance of those five questions is case-specific, and the Seventh Circuit has warned against "tak[ing] an overly rigid view of the formulation." *Id.* (quoting *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011)).

As defendant notes, Rule 9(b)'s "particularity" requirement applies to plaintiffs' claim for fraudulent concealment. *Squires-Cannon v. Forest Preserve District of Cook Cty.*, 897 F.3d 797, 805 (7th Cir. 2018) (citing *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 571 (7th Cir. 2007)). Under Wisconsin law, to prove a claim for fraudulent concealment, a plaintiff must establish: (1) defendant's failure to disclose a material fact; (2) defendant's intent to defraud; and (3) plaintiff's reliance on defendant's disclosures. *Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998) (citing *Goerke v. Vojvodich*, 67 Wis.2d

[5] If plaintiffs have any basis to claim a manufacturing defect, they should obviously move to amend as soon as possible because the likelihood of that motion being granted will rapidly diminish as the summary judgment deadline and trial date approach.

102, 226 N.W.2d 211 (1975); *Ollerman v. O'Rourke Co., Inc.*, 94 Wis.2d 17, 26 & 43 n.26, 288 N.W.2d 95 (1980)). Defendant argues that plaintiffs' fraudulent concealment claim should be dismissed because the complaint "fail[s] to identify any material omission with the requisite specificity," including identifying no failure by defendant to submit required adverse-event reports. (Mot. to Dismiss Br. (dkt. #10) 14.)

Here, plaintiffs have adequately pleaded their fraudulent concealment claim with sufficient particularity. They allege that defendant represented that the Align-S was "safe and effective," even though it knew or should have known that the Align-S: (1) had been the cause of many complications, not attributable to the implantation surgery itself; (2) was unproven as to safety; and (3) was neither safe nor effective. (Compl. (dkt. #1) ¶¶ 121-22.) Likewise, plaintiffs allege that Bard "knowingly made false claims in documents and marketing materials about the safety and quality of the Align-S," choosing to conceal the product's nature "to mislead Plaintiff, her physicians, hospitals and healthcare providers" so that they would use the Align-S. (*Id.* ¶¶ 125-27.) Finally, plaintiffs allege that both they and the medical providers relied on information from defendant, which omitted concerns about the Align-S. (*Id.* ¶ 129.)

Accordingly, plaintiffs may proceed past the pleading stage as to their fraudulent concealment claim. To the extent that plaintiffs are alleging that defendant somehow fraudulently concealed material information from the FDA, however, defendant is correct that plaintiffs have failed to identify any specific adverse-event reports that defendant failed to make to the FDA and defendant's motion will be granted as to this specific fraudulent concealment claim, if any.

C. Failure-to-Warn & Negligent Misrepresentation

Defendant next seeks dismissal of plaintiffs' failure-to-warn and negligent misrepresentation claims, contending that it "had no duty to warn Plaintiffs directly of any risks attendant with Align[-S]" under the learned-intermediary doctrine. (Mot. to Dismiss Br. (dkt. #10) 14-15.) Plaintiff argues that Wisconsin has yet to adopt the learned-intermediary doctrine and faults defendant for its reliance on the Seventh Circuit's "assumption" that the doctrine applies in *In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746 (7th Cir. 2018). (Opp'n (dkt. #19) 8.)

The learned-intermediary doctrine, which "enjoys broad support" outside Wisconsin, "holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *Zimmer*, 884 F.3d at 751. Nevertheless, Wisconsin appellate courts have not considered its application, leaving this court with no more definitive guidance than *Zimmer*. *Id.* at 749. In *Zimmer*, the Seventh Circuit concluded that "there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine for use in defective-warning cases like this one involving a surgical implant." *Id.* at 752. The court reached that conclusion by considering: (1) the only Wisconsin state court decision considering -- and ultimately applying -- the doctrine at the time; (2) the federal district courts that applied the doctrine under Wisconsin law; (3) the doctrine's broad application across the country; and (4) the doctrine's underlying rationale. *Id.* at 751-52. The doctrine is premised on the proposition that a learned intermediary is in the best position to

understand the patient's needs and meaningfully assess the benefits and risks, and is the patient's *only* gateway to the treatment.[6]

With no basis under Wisconsin case law to hold otherwise, this court would appear bound by the Seventh Circuit's holding in *Zimmer*. Regardless, the reasoning in *Zimmer* is sound, especially in the case of surgical implants. Accordingly, Bard had no duty to warn the plaintiffs *directly*, and defendant's motion to dismiss plaintiffs' claims on failure to warn and negligent misrepresentation will be granted with prejudice. To the extent that plaintiffs claim that defendant inadequately warned or was negligent with respect to material misrepresentations or omissions with respect to Delinda Karnes' medical providers, however, those claims survive defendant's motion. Plaintiffs identify the alleged deficiency in defendant's warning, and they allege that Delinda's "physicians would not have implanted the product in Plaintiff," either because they would have counseled against it or have been better equipped to inform her of the real risks, causing her to withdraw consent to the implant. (Compl. (dkt. #1) ¶¶ 112-16.) *See Zimmer*, 884 F.3d at 752 ("A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury." (quoting *Kurer v. Parke, Davis & Co.*, 272 Wis.2d 390, 679 N.W.2d 867, 876 (2004))).

[6] Given the absence of direction from the Wisconsin Supreme Court, the Seventh Circuit noted in *Zimmer* that one district court was "incorrect" when stating that "Wisconsin does not apply the learned intermediary doctrine." 884 F.3d at 751.

D. Breach of Implied and Express Warranties

Defendant seeks to dismiss plaintiffs' warranty claims as well, primarily on the grounds that plaintiffs improperly brought tort and warranty claims in one action. (Mot. to Dismiss Br. (dkt. #10) 15-16.) The Wisconsin Supreme Court has held that "it is inappropriate to bring an action for breach of warranty where a tort remedy is sought" because "[a] breach of warranty theory is encumbered with the ancient baggage of contract actions." *Austin v. Ford Motor Co.*, 86 Wis.2d 628, 644, 273 N.W.2d 233 (1979) (affirming trial court's ruling that "plaintiffs could not encumber the case by trying it on the duplicative theories of strict products liability and breach of implied warranty"). As that court explained in *Austin*,

> a warranty theory, if utilized or permitted, presents additional hurdles to the plaintiff. Where a strict liability action is alleged, the plaintiff need not prove specific acts of negligence by the defendant, and the defenses of notice of breach of warranty, disclaimer of warranty, and privity of contract are not available.
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> * * *
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> To assert a cause of action for breach of warranty or implied warranty in a tort action is not fatal to the pleader's cause, but the interest of justice and the adjudication of claims will be expedited if warranty claims, as such, are rejected and the case pursued as one for strict liability in tort.

Id. at 644-46 (internal citations omitted).

Plaintiffs' citation to *Dippel* (Opp'n (dkt. #19) 9-10) is unavailing. The *Austin* court relies on "the rationale of *Dippel*" to conclude that "where an action is brought in tort but denominated as breach of implied warranty, the cause of action may be maintained if sufficient facts are alleged to state a claim for strict liability in tort, but the warranty action as such should be dismissed." *Austin*, 86 Wis.2d at 645-46 (italics added). That is the

case here: plaintiffs have adequately pled a strict liability claim for design defect, so their warranty claims are dismissed.[7] *See Dippel*, 37 Wis.2d at 463 ("Because we have determined that physically injured users or consumers of unreasonably dangerous defective products should pursue their remedy under the rule of strict liability in tort, we conclude that the third cause of action in the complaint [premised on warranty] does not state facts sufficient to constitute a cause of action and the order sustaining the demurrer should be affirmed but with leave to plead over."); *see also Crosby v. Premier Marine, Inc.*, No. 01 C 50286, 2002 WL 596373, at *1 (N.D. Ill. Apr. 15, 2002) (noting that *Austin* "established that strict liability in tort actions precludes breach of warranty claims for physically injured users of unreasonably dangerous defective products" and dismissing warranty claims).

E. Negligent Infliction of Emotional Distress

Defendant also seeks dismissal of plaintiffs' negligent infliction of emotional distress claim for failure to "assert that the alleged emotional distress manifested in any physical injury." (Mot. to Dismiss Br. (dkt. #10) 17.) In response, plaintiffs contend that the alleged physical injury "is apparent and obvious" as "[t]he vaginal mesh perforated [Delinda's] vaginal wall which caused her great pain and emotional anguish." (Opp'n (dkt.

[7] Defendant raised two other reasons for dismissing plaintiffs' warranty claims: (1) a lack of privity between the parties; and (2) plaintiffs' failure to allege that they provided the requisite notice of their claim. (Mot. to Dismiss Br. (dkt. #10) 15-16.) Defendant may be correct on both scores. *See Staudt*, 16 F. Supp. 2d at 1030 (explaining that to establish a claim for breach of implied warranty, there must be privity of contract between the plaintiff and defendant) (internal citation omitted); *Blitz v. Monsanto Co.*, 317 F. Supp. 3d 1042, 1054-55 (W.D. Wis. 2018) (recognizing that Wisconsin's Uniform Commercial Code requires a buyer to "within a reasonable time after [discovering, or when he] should have discovered, any breach notify the seller of breach or be barred from any remedy" and that there was no exception to the notice requirement (quoting Wis. Stat. § 402.607(3)(a)). Regardless, the court need not reach these alternate grounds given dismissal of plaintiffs' warranty claims on other grounds.

#19) 10-11.) As an initial matter, to prove a claim for negligent infliction of emotional distress, a plaintiff must establish only three elements under Wisconsin law: "(1) that the defendant's conduct fell below the applicable standard of care, (2) that the plaintiff suffered an injury, and (3) that the defendant's conduct was a cause-in-fact of the plaintiff's injury." *Bowen v. Lumbermens Mut. Cas. Co.*, 183 Wis.2d 627, 632, 517 N.W.2d 432 (1994). As the Wisconsin Supreme Court explained in *Bowen*, "the injury a plaintiff must prove is severe emotional distress; *but the plaintiff need not prove physical manifestation of that distress*." *Id.* (emphasis added).

While both parties rely on *Nelson v. Monroe Reg'l Med. Ctr.*, 925 F.2d 1555, 1561 (7th Cir. 1991), for the proposition that Wisconsin law requires physical manifestation of emotional distress, the Wisconsin Supreme Court subsequently abandoned proof of physical manifestation in *Bowen* because: (1) it "denied recovery for *serious* emotional distress not accompanied by physical symptoms"; (2) "emotional distress can be established by means other than proof of physical manifestation"; (3) it "has encouraged extravagant pleading, distorted testimony, and meaningless distinctions between physical and emotional symptoms"; (4) the adversary process is the best test for claims; and (5) there was no evidence of a potential "deluge of litigation" in jurisdictions that already abandoned the physical manifestation or zone of danger rules. *Id.* at 653-54 (emphasis added). *See also* WIS JI -- Civil 1511 (2018) ("Emotional distress is compensable with or without physical injuries . . . ."). Accordingly, plaintiff did not need to plead a physical manifestation, and this portion of defendant's motion will also be denied.

F. Unjust Enrichment

Defendant similarly seeks dismissal of plaintiffs' unjust enrichment claim contending that they have not and allegedly cannot show "*any* direct benefit [conferred] on Bard" because plaintiffs did not purchase the Align-S "directly from Bard." (Mot. to Dismiss Br. (dkt. #10) 18 (emphasis added).) In response, plaintiffs argue defendant "received a benefit when Plaintiff chose the Align-S and directed her physician to purchase the device to be implanted inside her body." (Opp'n (dkt. #19) 11.)

As this court explained in *Blitz*,

> [u]nder Wisconsin law, unjust enrichment claims require proof of three elements: "(1) a benefit conferred on the defendant by the plaintiff; (2) appreciation or knowledge by the defendant of the benefit; and (3) acceptance or retention of the benefit by the defendant under circumstances making it inequitable to do so."

317 F. Supp. 3d at 1055 (quoting *Sands v. Menard*, 2017 WI 110, ¶ 30, 379 Wis.2d 1, 904 N.W.2d 789.

Here, while plaintiffs allege vaguely that (1) they paid for the Align-S and (2) Bard "accepted payment by Plaintiffs" (Compl. (dkt. #1) ¶¶ 177-78), they acknowledge that rather than being paid by plaintiffs, Bard "sold the defective product *to the Plaintiff's physician*" (Opp'n (dkt. #19) 12 (emphasis added)). *Cf. Blitz*, 317 F. Supp. 3d at 1055 (dismissing unjust enrichment claim where plaintiff purchased product from and conferred a benefit on third-party seller, not defendant). Accordingly, plaintiffs' unjust enrichment claim is dismissed.

G. Punitive Damages

Finally, defendant asks the court to dismiss plaintiff's claim for punitive damages as "a remedy, not the basis for a freestanding cause of action." (Mot. to Dismiss Br. (dkt. #10) 19 (quoting *Estate of Bain v. Transamerica Life Ins. Co.*, No. 18-C-311, 2018 WL 3328005, at (E.D. Wis. July 6, 2018)).[8] In response, plaintiffs agree that punitive damages are a remedy, not a cause of action, confirming that they "are sought as a remedy in this case," which "are properly included in the prayer for relief." (Opp'n (dkt. #19) 12.) Accordingly, this independent claim is dismissed, but plaintiffs may still seek punitive damages should the evidence at trial support it.

ORDER

IT IS ORDERED that defendant's motion to dismiss (dkt. #9) is GRANTED IN PART and DENIED IN PART as set forth above.

Entered this 16th day of April, 2019.

BY THE COURT:

/s/

_____
WILLIAM M. CONLEY
District Judge

[8] Defendant attributes this quote to *Becker v. Automatic Garage Door Co.*, 156 Wis.2d 406, 415, 456 N.W.2d 888 (Ct. App. 1990), which is cited by *Estate of Bain*. This is not the only incorrect citation in the parties' briefing. Accordingly, both sides are admonished going forward to doublecheck the citations to the record and to cases in future submissions before filling.